IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: FRANK AUSTRUP, ET AL.
SERIAL NO.: 09/744,866
FILED: April 2, 2001
FOR: CANCEL CELLS FROM BODY FLUIDS CONTAINING CELLS, ISOLATION THEREOF AND AGENTS CONTAINING THE SAME

GROUP ART UNIT: 1643
EXAMINER: Stephen J. Rawlings
ATTY. REFERENCE: GIES3001/ESS

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is a communication/amendment in the above-identified application.

☒ Small entity status under *37 CFR 1.9* and *1.27* is claimed.

☐ No additional fee is required.

The fee, if any, has been calculated as shown below:

Fee Basis	Number of Claims After Amendment	Highest Number Previously Paid For	Extra Claims	Small Entity	Full Fee
Total Claims		- [1]	= [3]	× $ 25 =	× $ 50 =
Independent Claims		- [2]	= [3]	× $100 =	× $ 200 =
☐ First Presentation of Proper Multiple Dependent Claim				+ $180 =	+ $360 =
			TOTAL		

[1] If less than 20 enter **20**. [2] If less than 3 enter **3**. [3] If less than 0 enter **0**.

☐ Please charge my **Deposit Account Number 02-0200** in the amount of **$** _____. A duplicate copy of this sheet is attached.

☒ A check in the amount of **$ 250.00** is attached. (Check No. 45523)

☐ The Commissioner is hereby authorized to charge any additional fees associated with this communication, including fees due under *37 CFR 1.16* and *37 CFR 1.17* or credit any overpayment to **Deposit Account Number 02-0200**. A duplicate copy of this sheet is attached.

☒ Also enclosed is/are: Appeal Brief

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Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application

Frank AUSTRUP, et al.

Application Number: 09/744,866

Filed: April 2, 2001

Examiner: Stephen J. Rawlings

Group Art Unit: 1643

Confirmation No.: 5636

For: CANCER CELLS FROM BODY FLUIDS CONTAINING CELLS, ISOLATION THEREOF AND AGENTS CONTAINING THE SAME

APPEAL BRIEF PURSUANT TO 37 C.F.R. 41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

A Notice of Appeal was filed on September 7, 2005 together with a Pre-Appeal Brief Request for Review. A Notice of Panel Decision was mailed on October 14, 2005. Thus, this Appeal Brief is due by November 14, 2005.

Compliance with 37 C.F.R. 41.37(c) follows:

37 C.F.R. 41.37(c)(1)(i)

Real Party In Interest:

The real party in interest is Professor Michael Giesing.

37 C.F.R. 41.37(c)(1)(ii)

Related Appeals and Interferences:

There are no related appeals and interferences.

37 C.F.R. 41.37(c)(1)(iii)

Status of Claims:

Claims 24 and 28 are rejected.

Claims 1-23 and 25-27 have been canceled.

37 C.F.R. 41.37(c)(1)(iv)

Status of Amendment Subsequent to Final Action:

The amendment to claim 24 and the addition of new claim 28 in the response of September 2, 2005 were entered in the Advisory Action of September 21, 2005.

37 C.F.R. 41.37(c)(1)(v)

Summary of the Claimed Invention:

The claims are directed to isolating disseminated tumor cells by screening body fluid selected from the group consisting of blood and bone marrow where the disseminated tumor cells are not modified prior to screening. See page 6,

line 11, through page 7, line 8. The term "disseminated" also includes micrometastasized and metastasizing tumor cells. See page 7, lines 3-7. Blood and bone marrow are mentioned at page 12, last line. Since disseminated tumor cells represent a considerable risk factor for the development of recurrence and metastasis (page 17, lines 9-12), the claimed method provides basis for recurrence prophylaxis (page 17, lines 7-9 and 28-30). The cells should be isolated essentially unaltered (page 5, lines 21-24). To this end, a number of modifications are excluded, in the applied claims. It is applicant's position that the exclusions in the claims are consistent with and find basis in the recitation at page 13, lines 25-30.

37 C.F.R. 41.37(c)(1)(vi)

Grounds of the Rejection to be Reviewed on Appeal:

The claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, and particularly on the basis that the inventors did not have in mind at the time the application was filed, carrying out the screening of claims 24 and 28 with unmodified disseminated tumor cells, i.e., without modification of the disseminated tumor cells, prior to screening by labeling, by attaching particles, by triggering aggregation, by triggering cluster formation, with antibodies, enzymes, lectins, other ligands, other receptors or crosslinking agents or by fixing.

37 C.F.R. 41.37(c)(1)(vii)

ARGUMENT:

It is applicant's contention that the following paragraph from page 13, lines 25-32 of the application as filed, shows the inventors had possession of the claimed invention at the time the application was filed.

> Furthermore it is also possible to modify the cancer cells in the cell suspension prior to the screening process, for example by labeling, by attaching particles, by triggering aggregation and/or cluster formation using, for example, suitable antibodies, enzymes, lectins, other ligands and/or receptors or crosslinking reagents, by fixing and by inducing other defined states.

Claims 24 and 27 track wording quoted above but indicate that the modifications described are not present.

It is applicant's contention that the above quoted language indicates that the applicants had in mind at the time the application was filed, two cases as follows:

Case (1): The cancer cells are not modified in the cell suspension prior to the screening process by labeling, by attaching particles, by triggering aggregation and/or cluster formation using antibodies, enzymes, lectins, other ligands and/or receptors or crosslinking reagents or by fixing.

Case (2): The cancer cells are modified in the cell suspension prior to the screening process by labeling, by attaching particles, by triggering aggregation and/or cluster formation using antibodies, enzymes, lectins, other ligands and/or

receptors or crosslinking reagents or by fixing.

The limitation in contention in the claims is Case (1) above.

It is applicant's contention that the words in the above quoted paragraph "it is also possible" (emphasis supplied) compel the interpretation that applicants had both Case (1) and Case (2) in mind at the time of filing of the application.

It would seem that the Office Action, Advisory Action and Decision from Pre-Appeal Brief Review are taking the position they take, on the basis that the exclusion of the claims is not explicitly set forth in the application as filed. That is not the test. The invention need not be described *ipsis verbis* in the application as filed. Ex parte Holt 19 U.S.P.Q.2d 1211 (Bd. App. 1991). The correct test in the context here is whether the language at page 13, lines 25-32 "it is also possible" discloses two alternatives where one of these alternatives is that of claims 24 and 28 of September 2, 2005. Cf. Ex parte Holt at page 1214. It is submitted that when the correct test is used, the contention of applicants is supported and the position in the Office Action is indicated to be incorrect.

Consider the following evidence that makes it is clear that the inventor had in mind as one alternative when the application was filed, carrying out the screening as set forth in claims 24 and 28, i.e., with unmodified disseminated tumor cells: Working Example 1 (page 35) shows screening of unmodified disseminated tumor cells. Furthermore, it is stated in the specification that "[h]igh purity of the isolated cancer cells and preservation by the isolation technique of the original state are particularly advantageous results of the invention" (page 32,

line 37 – page 33, line 1). However, modifying the cancer cells "by labeling, by attaching . . . and by inducing other defined states" (page 13, lines 25-32) would not preserve their original state (page 5, lines 21-36).

The Appendixes

Claims, evidence and related proceedings appendixes are attached.

Request for Reversal

Reversal of the rejection and allowance of claims 24 and 28 are requested.

Respectfully submitted,
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B&T: GIES3001/ESS

37 C.F.R. 41.37(c)(1)(viii)
Claims Appendix:

24. A method for isolating disseminated tumor cells from a cell-containing body fluid, consisting essentially of passing a cell-containing body fluid or part thereof that comprises a disseminated tumor cell through a screen having a mesh or pore width of about 15 to 30 μm to separate non-cancer cells from disseminated tumor cells, wherein the disseminated tumor cells are retained on the screen wherein the body fluid is selected from the group consisting of blood and bone marrow, wherein the disseminated tumor cells are not modified prior to screening by labeling, by attaching particles, by triggering aggregation, by triggering cluster formation, with antibodies, enzymes, lectins, other ligands, other receptors or cross linking agents or by fixing.

28. A method for isolating disseminated tumor cells from a cell-containing body fluid, consisting essentially of separating cellular components from non-cellular components in a body fluid that comprises a disseminated tumor cell to obtain a cell-containing fraction; resuspending the cell-containing fraction in a suspension medium; and passing the resuspended cell-containing fraction through a screen having a mesh or pore width of about 15 to 30 μm to separate non-cancer cells from disseminated tumor cells, wherein the disseminated tumor cells are retained on the screen, and wherein the body fluid

is selected from the group consisting of blood and bone marrow, wherein the disseminated tumor cells are not modified prior to screening by labeling, by attaching particles, by triggering aggregation, by triggering cluster formation, with antibodies, enzymes, lectins, other ligands, other receptors or cross linking agents or by fixing.

37 C.F.R. 41.37(c)(1)(ix)

Evidence Appendix:

No evidence entered by the examiner is relied on by applicant in this appeal.

37 C.F.R. 41.37(c)(1)(x)

Related Proceedings Appendix:

No related proceedings were identified pursuant to paragraph (c)(1)(ii).